

REMARKS

Claims 1,2, 4, 6-23, 25 and 27-43 are in the case and presented for reconsideration. The Specification has been amended. No new matter has been added.

The Specification has been objected to for the informality of having Table 1 as an Appendix. Accordingly, Table 1 has been incorporated into the drawings as new Fig. 6 in accordance with the Examiner's recommendation. The Specification has been amended in order to reflect this change accordingly. New formal drawings have been submitted to the Official Draftsperson. A copy is enclosed herewith.

Claims 1-2, 4, 7-11, 21-25 and 28-32 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Applicant's admission of the prior art in view of U.S. Patent 5,280,222 (von der Heide et al.) and U.S. Patent 4,538,082 (Hinke et al.) or U.S. Patent 4,639,670 (Normann). Claims 6, 12-18, 20, 27, 33-39 and 41 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Applicant's admission of the prior art in view of von der Heide et al. and Hinke et al. or Normann as applied to Claims 1, 4, 11, 21, 25 and 32 above, and further in view of U.S. Patent 4,247,601 (Wiegand). Claims 19 and 40 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Applicant's admission of the prior art in view of von der Heide et al. and Hinke et al. or Normann as applied to Claims 9 and 30 above and further in view of U.S. Patent 4,437,963 (Yeoman). Claims 21, 25, 28-32, 41 and 42 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Applicant's admission of the prior art in view of European Patent 0348557 (Honkura et al.). Claims 21, 24, 25, 28-32 and 41-43 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Applicant's admission of the prior art in view of U.S. Patent 6,270,591 (Chiriac et al.).

The Applicant's admission of the prior art, particularly that a position sensor of a medical device can be a Hall effect sensor, can be found in the Applicant's Specification, particularly on Page 1, Line 20 – Page 2, Line 22. As noted in the Applicant's Specification, the Hall effect sensor assembly described in U.S. Patent 5,558,091 suffer from problems such as

nonlinearities, saturation effects, hysteresis and temperature drifts. Additionally, as described in Applicant's Specification, Page 6, Lines 22-26, until the Applicant's claimed present invention, there have been no position sensors (which include Hall effect sensors) or sensor coils that have outer diameters smaller in size than the diameters of the known sensors described previously and that are capable of achieving performance measures such as maintaining a high degree of accuracy at high temperatures.

Additionally, each of the cited prior art references used in the prior art rejections outlined above are merely general teachings derived from unrelated fields when compared to the particular field of the Applicant's claimed present invention (the navigated medical device field). Particularly, von der Heide et al. describes an apparatus and method for controlling brushless electric motors and position encoders and indicating the position thereof. Although this reference does relate to Wiegand effect sensors, it is clear that these sensors are used specifically for linear or rotary acting electric motors. Column 1, Lines 15-18, Lines 35-38, and Lines 46-49. Moreover, there is no teaching or suggestion in this reference that Wiegand effect material could be used as part of a position sensor together with a medical device for determining position coordinates of a portion of the medical device and for ensuring that the position sensor maintains accuracy of ≤ 1 mm at temperatures greater than 75°C .

Hinke et al. describes a high-output magnetic field transducer suitable for use as a contactless ignition signal transducer (for example to replace mechanical breaker points in an ignition system for an externally ignited internal combustion engine) especially for automotive applications. Column 1, Lines 5-14. This reference lacks any teaching or suggestion of a medical device and position sensor combination wherein the position sensor has a core of Wiegand effect material and a winding so that position coordinates of a portion of the medical device can be determined while the position sensor maintains accuracy of ≤ 1 mm at temperatures greater than 75°C .

Normann describes a magnetic field sensor comprising Wiegand wires or similar distable magnetic elements that is capable of delivering an individual pulse at a higher energy

content than the pulse usually delivered by a single bistable magnetic element and in which the higher pulse energy is produced without a need for a supply of electric power. Column 3, Lines 43-49. Particularly, the magnetic field sensor of Normann is specifically applied to the field of optical fiber links, for example, for use with a light-emitting diode used as a transmitter diode in an optical fiber link. Column 5, Lines 13-16. There is no teaching or suggestion in this reference for using Wiegand effect material as part of position sensor together with a medical device for determining position coordinates of a portion of the medical device wherein the position sensor maintains accuracy of $\leq 1\text{mm}$ at temperatures greater than 75°C .

Wiegand describes a switchable magnetic device made of Wiegand wire for use in an improved switching device in order to respond to an external magnetic field to produce a pulse having improved signal to noise ratio and a larger peak amplitude. Column 1, Lines 61-65. Outside of this very general teaching, no description, suggestion or inference can be found in this reference that this material could be used as part of a position sensor for a medical device for determining position coordinates of the medical device for maintaining accuracy of $\leq 1\text{mm}$ at temperatures greater than 75°C .

Yeoman describes an apparatus for electrolyzing water. Although the Yeoman device utilizes Wiegand wire, it is clear that this device is directed to specifically to methods and apparatus for the electrolysis of water only. Column 1, Lines 35-42. There is nothing that can be found in this reference that would ever lead of one of ordinary skill to arrive at a position sensor and medical device combination wherein the position sensor and Wiegand effect material to determine position coordinates of a portion of the medical device so that the position sensor can maintain accuracy of $\leq 1\text{mm}$ at temperatures greater than 75°C .

Honkura describes a soft magnetic stainless steel having good cold forge ability and merely mentions that this particular soft magnetic stainless steel can be used in association with magnetic sensors. Column 1, Lines 1-8. Nothing in this reference teaches, suggests or even infers the use of Weigand effect material as part of a position sensor for a medical device for determining position coordinates of the medical device and maintaining its accuracy of $\leq 1\text{mm}$ at temperatures greater than 75°C .

Chiriac et al. describes amorphous and nanocrystalline glass-covered wires for applications in electrotechnics and electronics. Column 1, Lines 4-7. This reference lacks any teaching that either describes, suggests or infers a position sensor having Weigand effect material and medical device combination wherein the position sensor is used to determine position coordinates of the medical device while maintaining accuracy of ≤ 1 mm at temperatures greater than 75°C .

None of the cited prior art references, either alone or in combination with each other, teach, suggest or even infer a medical device and position sensor combination comprising a medical device having a body; a position sensor attached to a portion of the body wherein the position sensor has a core made of Wiegand effect material and a winding circumferentially positioned around the core, and wherein the position sensor is used for determining position coordinates of the portion of the body of the medical device such that the position sensor maintains accuracy of ≤ 1 mm at temperatures greater than 75°C , or a medical device and position sensor combination comprising a medical device having a body; a position sensor attached to a portion of the body wherein the position sensor has a core made of a high permeable material that is a magnetic material that produces a magnetic field that switches polarity and causes a substantially uniform voltage pulse upon an application of an external field, wherein the position sensor is used for determining position coordinates of the portion of the body of the medical device such that the position sensor maintains accuracy at ≤ 1 mm at temperatures greater than 75°C .

Based on the deficient teachings of each of the cited prior art references and their non-relation to the Applicant's field of endeavor, one of ordinary skill in the field of the Applicant's claimed present invention (the navigated medical device field) would never be led to rely on these references in the manner suggested by the Examiner. Additionally, the only way one of ordinary skill in this particular field could ever be led to arrive at the Applicant's claimed present invention, is by falling into the trap of using hindsight, i.e. using the Applicant's own Specification as a blueprint.

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Accordingly, by this Amendment and for the reasons listed above the Applicant's claimed present invention is neither anticipated by nor rendered obvious by these references and favorable action is respectfully requested.

Respectfully submitted,

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Amendments to the Drawings:

New formal drawings are being submitted to the Draftsperson. A copy is enclosed herewith.